

## REMARKS

Claims 1-34 are presently pending in the case. Claims 13 and 21-26 have been withdrawn from consideration.

Reconsideration of the present case in view of the remarks herein is requested.

### **Restriction**

Claims 13 and 21-26 have been withdrawn from consideration only until the generic claim from which they depend is indicated to be allowable.

### **Claim rejections under 35 USC 103(a)**

The Examiner rejected claims 1-12, 14-20, and 27-34 under 35 USC 103(a) as being unpatentable over U.S. Patent 5,921,236 to Ohki et al (hereinafter Ohki et al) in view of U.S. Patent 5,881,719 to Gottenauer et al (hereinafter Gottenauer et al). The rejection is traversed.

Ohki et al does not render claim 1, for example, unpatentable. Claim 1 is to an aerosolization apparatus comprising, inter alia, a puncturing mechanism comprising an alignment guide and a puncture member, wherein the alignment guide comprises a surface adapted to contact a capsule while the puncture member is advanced into the capsule to create an opening in the capsule and wherein at least a portion of the surface is sloped at an angle which is less than 55 degrees relative to the longitudinal axis of the capsule. Ohki et al does not disclose a surface that is sloped as claimed. Therefore, Ohki et al does not render claim 1 unpatentable.

Claim 1 is also not rendered unpatentable by Ohki et al and Gottenauer et al. Gottenauer et al does not teach or suggest a puncturing mechanism. Instead, Gottenauer et al teaches a housing means for pressing out cavities (see abstract). There is no puncture mechanism in the system taught by Gottenauer et al. Therefore, if one were to substitute the mechanism of Gottenauer et al for the system of Ohki et al, as suggested by the Examiner, the resulting device would be devoid of a puncture member. The Examiner may not pick and choose portions of a reference in an attempt to reconstruct Applicant's claimed invention. Instead, the Examiner must

consider the teachings of the references as a whole. When considering the teachings of Ohki et al and Gottenauer et al as a whole, it is clear that one of ordinary skill in the art would not have been motivated to modify Ohki et al in a manner that would arrive at Applicant's invention. Thus, the combination of references does not render claim 1 unpatentable.

Applicant requests withdrawal of the rejection of claim 1 and claims 2-19 depending therefrom.

Independent claim 20 is also not rendered unpatentable by Ohki et al and Gottenauer et al. Claim 20 is to an aerosolization apparatus comprising, inter alia, a puncturing mechanism comprising an alignment guide and a puncture member, wherein the alignment guide comprises a surface adapted to contact a capsule while the puncture member is advanced into the capsule and wherein the surface comprises one or more protrusions for contacting the capsule. Neither Ohki et al nor Gottenauer et al disclose an alignment guide surface with protrusions, as claimed. Therefore, Ohki et al and Gottenauer et al do not render claim 20 or depending claims 21-28 unpatentable.

Claim 29 is not rendered unpatentable by Ohki et al and Gottenauer et al either. Claim 29 is to a method of providing access to an aerosolizable pharmaceutical formulation, the method comprising, inter alia, contacting a capsule with the surface of an alignment guide, the surface being sloped at an angle which is less than 55 degrees relative to the longitudinal axis of the capsule. Ohki et al and Gottenauer et al do not teach or suggest at least this feature, as discussed above. Thus, claim 29 is not rendered unpatentable by Ohki et al and Gottenauer et al. Claim 30 depends from claim 29 and is also not rendered unpatentable by Ohki et al and Gottenauer et al.

In addition, claim 31 is not rendered unpatentable by Ohki et al and Gottenauer et al. Claim 31 is to a method of providing access to an aerosolizable pharmaceutical formulation, the method comprising, inter alia, contacting a capsule with the surface of an alignment guide, the surface comprising one or more protrusions for contacting the capsule. Ohki et al and Gottenauer et al do not teach or suggest this feature, as discussed above. Therefore, claim 31 and claim 32 which depends therefrom are not rendered unpatentable by Ohki et al and Gottenauer et al.

Ohki et al and Gottenauer et al also do not render claim 33 unpatentable. Claim 33 is to a method of aerosolizing a pharmaceutical formulation, the method comprising, inter alia, contacting the capsule with the surface of an alignment guide, the surface being sloped at an angle which is less than 55 degrees relative to the longitudinal axis of the capsule and/or having one or more protrusions for contacting the capsule. As discussed above, Ohki et al and Gottenauer et al do not teach or suggest either of these features. Therefore claim 33 is not rendered unpatentable by Ohki et al and Gottenauer et al. Claim 34 depends from claim 33 and is also not rendered unpatentable by Ohki et al and Gottenauer et al.

**Conclusion**

The claims are allowable for the reasons given above. Thus, the Examiner is respectfully requested to reconsider the present rejections and allow the presently pending claims. Should the Examiner have any questions, the Examiner is requested to call the undersigned at the number given below.

Respectfully submitted,

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